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106TH CONGRESS
2D SESSION

H. R. 4705

To provide for the recoupment of a portion of the Federal investment in research and development supporting the production and sale of pharmaceutical, biologic, or genetic products.

IN THE HOUSE OF REPRESENTATIVES

JUNE 21, 2000

Mr. CAPUANO (for himself and Mr. STARK) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committees on Science, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To provide for the recoupment of a portion of the Federal investment in research and development supporting the production and sale of pharmaceutical, biologic, or genetic products.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Public Investment Recovery Act of 2000''.

SEC. 2. RECOUPMENT REQUIREMENT.

Each transaction entered into by an agency of the Federal Government under which Federal support is provided for research and development which leads or may lead to the production and sale of a pharmaceutical, biologic, or genetic product shall include provisions requiring that payments described in section 4 shall be paid annually to the Federal agency for deposit in the Public Investment Recovery Trust Fund established under section 6.

SEC. 3. PUBLIC INVESTMENT RECOVERY BOARD.

(a) ESTABLISHMENT.—There shall be established a Public Investment Recovery Board, consisting of—

(1) a chairperson, who shall be an employee of the National Science Foundation appointed by the Director of the National Science Foundation;

(2) a representative of the Internal Revenue Service;

(3) a representative of the Food and Drug Administration;

(4) a representative of the Department of the Treasury;

(5) a representative of the National Institutes of Health;

(6) a representative of the Office of Science and Technology Policy; and

(7) 3 nonvoting members appointed under subsection (b)(1).

(b) NONVOTING MEMBERS.—

(1) APPOINTMENT.—The President shall appoint 3 nonvoting members to the Board from among appropriate nonprofit scientific and medical societies, such as the American Association of Medical Colleges, the American Pharmaceutical Association, and the Biotechnology Industry Organization. The President shall seek to ensure broad representation of appropriate points of view in making appointments under this paragraph.

(2) TERMS.—Members appointed under paragraph (1) shall serve 3-year terms, except that of the initial appointments 1 member shall be appointed to a 1-year term and 1 member shall be appointed to a 2-year term.

(3) COMPENSATION.—Members appointed under this subsection shall receive no compensation for service on the Board.

(c) FUNCTIONS.—The Board shall—

(1) determine, for purposes of section 4(a), the total amount of profits that have been received with respect to a pharmaceutical, biologic, or genetic product, including profits received by a person not

a party to the transaction with the Federal agency; and

(2) make calculations under section 5 of the proportion of Federal support for research and development which lead to the production and sale of a pharmaceutical, biologic, or genetic product.

(d) ADMINISTRATIVE SUPPORT.—The National Science Foundation shall provide necessary administrative support for the Board and its staff.

SEC. 4. AMOUNT OF PAYMENT REQUIRED.

(a) GENERAL RULE.—Except as provided in subsection (b), the amount that shall be required to be paid under section 2 to a Federal agency shall be equal to the total amount of profits determined by the Board under section 3(c)(1) to have been received with respect to the pharmaceutical, biologic, or genetic product up to the time of payment, multiplied by the percentage calculated by the Board under section 5.

(b) LIMITATION.—No annual payment shall be required under this Act that exceeds 20 percent of the profits determined by the Board to have been received during the year for which the payment is made.

(c) EXPIRATION OF REQUIREMENT.—The requirement to make payments under this Act shall expire on

the expiration of the initial patent issued for the pharmaceutical, biologic, or genetic product.

SEC. 5. CALCULATION OF PERCENTAGE.

The Board shall calculate, for each pharmaceutical, biologic, or genetic product sold for which Federal support was provided through a transaction described in section 2, the percentage that Federal support represents of the total research and development that supported the production and sale of the product.

SEC. 6. PUBLIC INVESTMENT RECOVERY TRUST FUND.

(a) ESTABLISHMENT.—The Secretary of the Treasury shall establish an account in the Treasury to be known as the ''Public Investment Recovery Trust Fund'', into which shall be deposited all payments received by the Federal Government pursuant to this Act.

(b) PURPOSES.—Amounts in the Trust Fund may be used, to the extent provided in advance in appropriations Acts, for the following purposes:

(1) Not more than 2 percent may be used by the Food and Drug Administration or the National Institutes of Health to support research on the comparative efficiency and effectiveness of pharmaceutical, biologic, or genetic products and the reporting thereof.

(2) Not more than—

(A) 20 percent, in each of the first 5 fiscal years after the date of the enactment of this Act; and

(B) 3 percent, in subsequent fiscal years, may be used to help pay the administrative expenses of carrying out this Act.

(3) Not more than 20 percent may be used by the National Institutes of Health to support pharmaceutical, biologic, or genetic research and development, unless no Medicare prescription drug benefit has been enacted by the Congress, in which case the remainder of the funds in the Trust Fund may be used for the purpose under this paragraph.

(4) If a Medicare prescription drug benefit has been enacted by the Congress, the remainder of the funds in the Trust Fund shall be used for financing such prescription drug benefit, except that any amounts available in the Trust Fund in excess of amounts required for financing such prescription drug benefit may be used for the purpose stated in paragraph (3).

SEC. 7. DEFINITIONS.

In this Act—

(1) the term ''Board'' means the Public Investment Recovery Board established under section 3;

(2) the term ''Federal support'' includes direct Federal research and development funding support, the cost of research and development conducted by the Federal Government and used in support of the production and sale of a product, and the relevant proportion of Federal funding support for any nonprofit organization conducting research and development that is used in support of the production and sale of a product; and

(3) the term ''pharmaceutical, biologic, or genetic product'' has the meaning given the term ''covered outpatient drug'' under section 1927(k)(2) of the Social Security Act (42 U.S.C. 1396r–8(k)(2)).

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